

## **Remarks**

Claims 1, 3-8, 10-21, and 23-40 are pending in this application. Claims 1, 17, and 32 have been amended, and no claims have been added or canceled. Reconsideration of this application is respectfully requested in light of the above amendments and the following remarks.

### **Rejection of Claims 1, 3-8, 10-21, and 23-40 Under 35 U.S.C. § 112, ¶ 1**

Claims 1, 3-8, 10-21, and 23-40 have been rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement due to reciting the phrases “. . . wherein only some of the cells are in contact with the anchors . . .” and “. . .the substrate configured to . . .” In response, claims 1, 17, and 32 have been amended to delete these two phrases. These amendments have been made solely to address the rejection under 35 U.S.C. § 112. Accordingly, Applicants respectfully request reconsideration and withdrawal of this rejection.

### **Rejection of Claims 1, 3-8, and 10-16 Under 35 U.S.C. § 112, ¶ 2**

Claims 1, 3-8, and 10-16 have been rejected under 35 U.S.C. § 112, second paragraph, as being indefinite due to claim 1 reciting (1) “. . .the substrate configured to permit the monolayer to detach . . .” and (2) “. . .only some of the cells are in contact with the anchors . . .” In response, Applicants have deleted phrase (1) from claim 1 and now recite “the cardiac cells cultured *in vitro* to form a confluent monolayer between the anchors which subsequently detaches from the substrate and self-organizes to form the three-dimensional cardiac muscle construct.” In addition, Applicants have deleted phrase (2) from claim 1 and now recite “wherein at least some of the cells are in contact with the anchors and attach thereto.” These amendments have been made solely to address the rejection under 35 U.S.C. § 112. Therefore, reconsideration and withdrawal of this rejection is also respectfully requested.

**Rejection of Claims 1, 3-8, 10-21, and 23-40**  
**Under 35 U.S.C. § 112, ¶ 2**

Claims 1, 3-8, 10-21, and 23-40 have been rejected under 35 U.S.C. § 112, second paragraph, as being indefinite due to the claimed anchors. In particular, the Examiner states that “[i]t appears that the anchors may actually be serving as a scaffold-like structure” (*see* Office Action dated May 31, 2007, p. 4). In response, Applicants have amended independent claims 1, 17, and 32 to recite “at least two anchors secured to the substrate in spaced relationship” and “cardiac cells provided on the substrate to form a cardiac muscle construct without an exogenous scaffold material in a contractile region thereof, wherein at least some of the cells are in contact with the anchors and attach thereto.” Support for this amendment can be found, for example, at p. 6, lines 6-11 of the specification, and in FIGS. 1A-1D. These amendments have been made solely to address the rejection under 35 U.S.C. § 112.

Therefore, at least some of the cells are in contact with the spaced-apart anchors which, as is known to those skilled in the art, function as spaced, discrete attachment points for the developing tissue. In contrast, a scaffold is understood by those skilled in the art to be a three-dimensional growth surface into which the cells are introduced and which serves to at least partially stand in place of naturally generated extracellular matrix materials integral with the contractile elements of the forming construct (*see* Background Art). In the system and method of the present invention, cardiac cells are provided on the substrate without an exogenous scaffold material in the contractile region of the self-organizing tissue, as now clarified by the claim language, which precludes the anchors from being confused with a prior art scaffold as the Examiner contends. Furthermore, Applicants’ specification is clear on the distinction between anchors and scaffold material, especially since these are terms well known in the art.

The Examiner also states that “the spatial relationship of the anchors appears to be essential for the growth of cells in the invention and should be clearly defined” (*see* Office Action dated May 31, 2007, p. 4). Applicants assert that claims 1, 17, and 32 do

clearly define the spatial relationship of the anchors, in that these claims recite “at least two anchors secured to the substrate in spaced relationship,” “cardiac cells provided on the substrate . . . wherein at least some of the cells are in contact with the anchors and attach thereto,” and “the cardiac cells cultured *in vitro* to form a confluent monolayer between the anchors.” Furthermore, Applicants’ claims now recite the absence of an exogenous scaffold material in a contractile region of the construct which further clarifies the spatial relationship of the system. Accordingly, reconsideration and withdrawal of this rejection is respectfully requested.

**Double Patenting**

Claims 1, 3-7, 10-21, 23-27, 29, 32-36, and 40 have been rejected under nonstatutory obviousness-type double patenting as being unpatentable over claims 1-3, 5-9, 12-13, 15-19, 21-23, 26, and 28-31 of U.S. Patent No. 6,207,451. Applicants acknowledge this rejection, and reserve the right to file a terminal disclaimer in order to overcome the rejection once the claims are otherwise in allowable condition.

## **Conclusion**

In summary, Applicants believe that the claims meet all formal and substantive requirements and that the case is in appropriate condition for allowance. Accordingly, such action is respectfully requested. If a telephone conference would expedite allowance of the case or resolve any further questions, such a call is invited at the Examiner's convenience.

Please charge any fees or credit any overpayments as a result of the filing of this paper to our Deposit Account No. 02-3978.

Respectfully submitted,

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